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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,068	02/26/2002	Christopher H. Evans	018484-002121US	3205

7590 03/24/2005

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EXAMINER	
LIETO, LOUIS D	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/086,068	EVANS ET AL.	
	Examiner	Art Unit	
	Louis D Lieto	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-157 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-157 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response to the prior restriction/election requirement, received on 1/19/2005, is acknowledged. However, upon further review of the record it is noted that Applicant has submitted two different claim sets: the first set was filed on 2/26/2002, and contained claims 1-142, it was amended with a preliminary amendment, also filed on 2/26/2002 to add claims 143-157; the second set of claims, filed on 8/12/2002, contains only claims 1-142 and was used as the basis for the prior restriction requirement. There is no record or indication that amended claims 143-157 were cancelled or withdrawn. Given the confusion in the record as to which claims are to be examined, the prior Election/Restriction requirement is withdrawn and a new Election/Restriction requirement follows:

Applicant is requested to file an updated claim set with their response, indicating the status of claims 1-157.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-54, drawn to a method of treating rheumatoid arthritis, which comprises delivery of a DNA sequence to a host, classified in class 514, subclass 44.

II. Claims 55-108, drawn to a method of treating systemic lupus erythematosus, which comprises delivery of a DNA sequence to a host, classified in class 514, subclass 44.

III. Claims 109-130, drawn to drawn to a method of treating a connective tissue disorder, which comprises delivery of a DNA sequence to a host, classified in class 514, subclass 44.

IV. Claims 131-142, drawn to a mammalian cell comprising a recombinant retroviral vector, which comprises a DNA sequence encoding IRAP, classified in class 435, subclass 325.

V. Claims 143-157, drawn to a method of inhibiting an IL-1 induced biological response in a mammal, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III and V are patentably distinct inventions for the following reasons. In the instant case the different invention of group I is to a method of treating rheumatoid arthritis, group II is to a method of treating systemic lupus erythematosus, group III is to a method of treatment of a connective tissue disorder, and group V is to a method of inhibiting an IL-1 induced biological response. The diseases of groups I, II, and III are substantially different from each other, affecting different tissues and organs, involving different symptoms, have different frequencies of occurrence, and different ages of onset. The method group V differs the methods of diseases treatment of groups I-III because none of them require an inhibition of IL-1. Further, a method of inhibiting an IL-1 induced biological process in a mammal could be accomplished by inhibiting IL-1 induced fever, slow-wave sleep, or the release of a variety of neuropeptides, none of which are unique to or required for the methods of I-III. None of the inventions requires the others.

Inventions I-III, IV and V are patentably distinct inventions for the following reasons. In the instant case the different inventions of groups I-III are to methods of treating disease, the invention of group V is to a method of inhibiting an IL-1 induced biological response in a

mammal, while the invention of group IV is to a mammalian cell comprising a recombinant retroviral vector, which comprises IRAP. The methods of treating disease of groups I-III and the method of inhibiting an IL-1 induced biological response in a mammal of group V can be practiced without the mammalian cell of group IV. Further, the mammalian cell of group IV can be used as an *in vitro* research tool in a manner unrelated to the study of disease.

Furthermore, searching the inventions of groups I-V together would impose a serious search burden. In the instant case, the search of methods of treatment of disease, a method of inhibiting IL-1 and the mammalian cells are not quite different. The methods are structurally and functionally different from the mammalian cells and from each other. The mammalian cells could be made and used in multiple different and independent ways; thus, the mammalian cell of group IV encompasses a separate search of the art. Finally, the methods of treatments of disease of groups I-III and a method of inhibiting IL-1, of group V, are functionally distinct from each other. Thus, the search of groups I-V is not co-extensive. As such, it would be burdensome to search the inventions of groups I-V together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and because each requires a separate search of the prior art, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: The inventions of groups I -V list the following patentably distinct species of vectors in which the DNA sequence is subcloned:

a) non-viral vector

b) a retroviral vector

c) adenovirus vector

d) an adeno-associated vector

e) herpes simplex virus vector

f) an SV40 vector

g) polyoma virus vector

h) papilloma virus vector

i) picornavirus vector

j) vaccinia virus vector

k) Moloney murine leukemia virus

l) MFG-IRAP

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-157 are generic.

The inventions of groups I-III, and V list the following patentably distinct species of DNA sequences encoding a biologically active gene product:

a) IL-1 receptor antagonist protein

b) IL-4

c) IL-10

d) IL-1 soluble receptor

e) TNF α soluble receptor

f) TIMP

g) soluble ICAM-1

h) soluble CD44

i) soluble CD18

j) superoxide dismutase

k) IGF α

l) TGF β

m) collagen

n) IRAP

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-130, and 143-157 are generic.

The inventions of group III list the following patentably distinct species of connective tissue diseases or disorders:

a) Sjorgen's syndrome

b) polymyositis-dermatomyositis

c) systemic sclerosis

d) vasculitis syndromes

e) juvenile rheumatoid arthritis

f) ankylosing spondylitis

g) psoriatic arthritis

h) osteoporosis

i) osteogenic imperfecta

j) Paget's disease

k) inflammatory bowel disease

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 122-130 are generic.

Applicant is reminded that they must elect a species even if it reads only on an unelected group.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Lou Lieto whose telephone number is (571) 272-2932. The examiner can normally be reached on Monday-Friday, 9am-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571)-272-0735. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Patent applicants with problems or questions regarding electronic images that can be viewed in the PAIR can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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